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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,558	ANKER ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,35-41,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,19, 29-31,35,36,38,39 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5-18,20-28,37,40,41,46 and 47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/21/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction:

1a. Applicant's election with traverse of the invention of Group I, (claims 1-3, 19, 29-31, 35-36, 38-39 (in part), and claim 4), filed on 05 February 2004 is acknowledged.

1b. Claims 1-31, 35-41, 46-47 are pending. Claims 32-34 and 42-45 have been cancelled. Claims 1-2, 19, 29-31, 35-36, 38-39, will be searched and examined in so far as they pertain to a method of administering to a patient a compound that inhibits the effect of aldosterone, claims 3 and 4 will be searched and examined in full. Claims 5-18, 20-28, 37, 40-41 and 46-47 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Applicants' first ground of traversal is on the grounds that the restriction requirement is improper because the independent claims in this present application are sufficiently linked as to from a single general inventive concept. Applicants argue that the common technical feature of treating weight loss by administering an inhibitor of sympathetic nervous system activity, which links the independent claims is not known in the prior art. The second ground of traversal is that the claims meet the unity of invention standards for Markush practice, because claims have the common property/activity of decreasing sympathetic nervous system activity and are all recognized as being sympathetic nervous system blockers. Thus, Applicants argue that these are known compounds with art recognized activities and classification. Applicants' third ground of traversal is that dividing a single claim into multiple inventions is improper and that proper practice would have been to require an election of species.

Applicant' fourth ground of traversal is that the examiner has divided generic claims into different groups based on the description in the specification of what molecules can be used, thus imposing limitations not present in the claims.

Finally Applicants submit that the instant application has been pending for three years, and in that time the examiner has issued two restriction requirements and a letter requesting clarification and that a first action of the merits has not yet been issued. Applicants maintain that the present restriction requirement is further delaying the prosecution and request rejoinder of the claims and examination on the merits.

These grounds of traversal have been fully considered but are not deemed persuasive. With respect to Applicants' first ground of traversal, as was set forth in the restriction requirement mailed on 06 January 2004, page 7, second paragraph, the method recited in claim 1, said method of administering an agent that reduces sympathetic nervous activity, is not itself an advance over the prior art, because Mueller et al. (Journal of clinical of investigations, Vol.65, pages 338-346, 1980), describe a method of administering propranolol, (a beta-adrenergic receptor-blocking agent), to patients, and demonstrate that propranolol decreases sympathetic nervous activity, (see abstract and page 343, second paragraph). It is an inherent property of propranolol to reduce sympathetic nervous system. Instant claim 1 recites the administration of an agent which reduces sympathetic nervous system to treat weight loss. However, newly discovered result of a known process directed to the same purpose are not patentable because such result is inherent. See MPEP 2112-2112.02.

With respect to Applicants' second ground of traversal, the claims of the instant application fail to meet the unity of invention standards for Markush practice, because the art does not recognize the recited compounds as having the same activity neither does the art classify the recited compounds together. As was explained on page 8, second paragraph of the restriction requirement mailed on 06 January 2004, the methods of groups 1-16 administer compounds that do not share a common structure or activity. For example, the art would not classify "spirononlactone" recited in claim 4, as an agent that reduces sympathetic nervous system, but rather as an agent that inhibits the effect of aldosterone. Likewise, the art recognizes erythropoietin, recited in claim 2, as a glycoprotein that stimulates formation erythroid precursors to generate red blood cells. Thus, one of ordinary skill in the art would not recognize the compounds recited in instant claims as having a common property/activity, neither do these compounds share a common structure.

With respect to Applicants' third ground of traversal, since the invention recited in claim 1 is not itself an advance over prior art, and since the compounds recited in some of the claims have no common structure or property, some single claims belong into multiple inventions. Contrary to Applicants' argument the compounds recited in these claims are not species to a genus group. The compounds have no common structure or activity, therefore, these compounds are patentably distinct and are subject to restriction requirement, rather than species election.

With respect to Applicants' fourth traversal, the examiner is not imposing limitations not recited into the claims, but rather is reading the claims in light of the

specification. Claims 1, 19, 35 and 38 recite ".....an agent which reduces sympathetic nervous system activity...", however this phrase is vague and renders the claims indefinite. The sympathetic nervous system is a very complex system and directly or indirectly affects almost every structure in the body (e.g. heart, kidneys, blood vessels, stomach and intestines). Furthermore, disparate compounds with no common structure or function may reduce one activity or another of the sympathetic nervous system. Thus, claims 1, 19, 35 and 38 are read in light of the specification for clarification.

Finally, any delay is regretted, however, Applicants did not respond to the first restriction requirement, which prompted the issuance of the non-responsive letter. Applicants' request to issue an office action on the merits is granted and said office action follows. Furthermore, Applicants' intention to petition for review of this restriction requirement is acknowledged.

However, the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-31, 35-41, 46-47 are pending. Claims 1-2, 19, 29-31, 35-36, 38-39, will be searched and examined in so far as they pertain to a method of administering to a patient a compound that inhibits the effect of aldosterone, claims 3 and 4 will be searched and examined in full. Claims 5-18, 20-28, 37, 40-41 and 46-47 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Claim objections:

2a. Claims 2, 36, 39 and 41are objected to because of the following informalities:

Claims 2, 36, 39 and 41 are objected to because it is recites non-elected inventions.

Appropriate correction is required.

Specification:

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

3a. As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid

sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Drawings:

4a. The drawings are objected to, because they are not in compliance with 37 CFR 1.84 (o). This application contains 5 drawings, however, the drawings fail to meet the standards under37 CFR 1.84 (o), because the legends describing these drawings are not legible. Furthermore, figure 1 itself is neither legible nor visible. The X-axis of figure 2 is also not legible. Appropriate correction is required.

Claim rejections-35 USC § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1, 2, 3, 4, 19, 29-31, 35-36, 38-39 and 41 are rejected under 35 U.S.C. 112, first paragraph, while being enabling for a method of treating chronic heart failure (CHF) by administering spironolactone, does not reasonably provide enablement for a method of treating weight loss due to "all" possible underlying diseases by administering "all" possible agents which reduce sympathetic nervous system activities, or by administering the agents recited in claim 4, or by administering "all" possible compounds that inhibit the effect of aldosterone, or by administering an aldosterone antagonists.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 1, 2, 3, 19, 35, 36, 38-39 and 41 are single means claims (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: "A single means claim, i.e. where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph." (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). Instant claims 1, 19, 35 and 39 recite no material limitations for the agent which reduces sympathetic nervous system activity, nor which activity of the sympathetic nervous system should be inhibited. Claims 2, 3, 36, 39 and 41 recite no material limitations for the agent that inhibit the effects of aldosterone. Therefore, the claims encompass every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. The claimed invention encompasses the administration of agents not envisioned or described in the specification, and neither does the specification disclose how these agents can be distinguished from each other. The specification only enables the administration of spironolactone to treat chronic heart failure (CHF), (see page 55, Example 12). The art recognizes that patients with congestive heart failure are often treated with an ACE inhibitor together with spironolactone, (see the RALES investigators' study, American Journal of Cardiology, Vol.78, pages 902-907, 1996). Therefore, in the instant application it is understood that the single patient used for the spironolactone study, is also taking an ACE inhibitor for his chronic heart failure. The specification discloses

that the administration of spironolactone improves the patient's exercise capacity and increases body weight by 2%, without development of any side effects, however, the specification does not disclose how long is said patient on the spironolactone treatment, (see pages 56-57). Spironolactone is a diuretic agent that blocks the renal tubular actions of aldosterone. Therefore, spironolactone possesses properties that may differ structurally, chemically and physically from other known agents which reduce sympathetic nervous system activity or agents which inhibit aldoserone effect. With respect to the "effective amount", recited in the claims, the specification states that spironolactone may be given at between 12.5 mg and 300 mg per day, orally, (page 4, lines 14-15). However, the patient in the instant specification receives 25 mg/day spironolactone, and Applicants have not shown whether higher dosages of this drug are save for the patient. The RALES researchers disclose that at day 9 and week 4 visits, patients receiving 75 mg of spironolactone lost more weight than did patients receiving lower dosage, although this dose response was not observed at later visits, (see page 904, column 1). Therefore, higher doses of spironolactone might have undesirable effects. To practice the instant invention in a manner consistent with the breadth of claims 1, 2, 3, 19, 35, 36, 38, 39 and 41 would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of all the encompassed agents which reduce sympathetic nervous system activity or other agents which inhibit aldoserone effect, and test if these agents are effective in treating "all" possible underlying diseases that cause weight loss. One of ordinary skill also would have to

conduct controlled studies to determine the correct dosages of the recited compounds to use. It is this additional characterization of the disclosed protein that is required in order to obtain the functional and structural data needed to permit one to practice the claimed method that constitutes undue experimentation.

With respect to claim 4, the instant specification does not disclose that the administration any of the recited agents other than spironolactone, actually was effective in treating underlying disease. With respect to claims 29 and 30, instant specification only discloses the treatment of one patient suffering from chronic heart failure, by administering spironolactone. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, the quantity of experimentation to determine which of the enormous number of agents which reduce sympathetic nervous system activity or which inhibit aldoserone effect, would be effective in treating underlying disease which cause weight loss, as encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little. Furthermore, one of ordinary skill in the art would not know the reduction of which activities of the sympathetic nervous system would result in treating weight loss,

because the instant specification provides no guidance as to which activities of said system should be inhibited in order to treat said disease. Likewise, one of ordinary skill in the art would not predict whether spironolactone or agents that have similar actions could be effective in treating weight loss due to diseases other than heat disease.

Thus, in light of the nature of the invention, the state of the art, the high level of unpredictability in the art, the lack of direction or working examples in the specification, and the high quantity of experimentation that would be required to practice the claimed invention, it is concluded that undue experimentation would be required to use the instantly claimed invention.

Therefore, instant specification is only enabling for a method of treating to chronic heart failure (CHF) by administering spironolactone.

5b. Claims 35-36,and 38-39 are rejected under 35 U.S.C. 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.

Claims 35-36 are drawn to a method of treating or preventing weight loss due to aging process by administering an effective amount of an agent which reduces sympathetic nervous system activity or by administering a compound which inhibits the effect of aldosterone. Claims 38-39 of the instant Application are drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of an agent which reduces sympathetic nervous system activity or by administering a compound which inhibits the effect of aldosterone. However, the

specification as filed does not disclose a single case where the treatment of either an agent that reduces a sympathetic nervous system activity or an agent that inhibits the effects of aldosterone is shown to enhance the exercise performance of a healthy individual or to treat weight loss due to aging. The instant specification states that a method of treating or preventing weight loss due to the aging process in a patient by administering compounds, is one of the embodiments of the instant invention (see page 14, lines 19-24). Likewise, instant specification states that a seventh aspect of the invention provides a method of enhancing exercise performance in a healthy individual the method comprising administering to the individual an effective amount of any one or more of a compound that inhibit the effect of aldosterone, (see pages 15-16). However, nowhere in the instant specification do Applicants disclose the administration of any compound to a healthy individual, and demonstrate that said administration results in exercise enhancement, nor does the specification disclose the prevention or treatment of weight loss due to aging by administering any compound. The instant specification merely makes the above statements but provides no evidence to support them. The instant specification does not conduct the necessary experiments with proper controls to show that the administration of a compound which inhibits the effect of aldosterone enhances exercise performance in healthy individuals, or treats or prevents weight loss due to aging, while not causing any detrimental side effects. Furthermore, the specification does not disclose how much is an effective amount, which is a very important consideration when treating human beings. There is no indication in the instant specification that any compound was actually administered to enhance exercise

healthy individuals, or to prevent or treat weight loss due to aging. Thus, in light of the nature of the invention, the state of the art, the high level of unpredictability in the art, the lack of direction or working examples in the specification, and the high quantity of experimentation that would be required to practice the claimed invention, it is concluded that undue experimentation would be required to use the instantly claimed invention. Accordingly, claims 35-36 and 38-39 are not supported with an enabling disclosure.

5b. Claims 1, 2, 3, 4, 19, 35, 36, 38, 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Instant claims are drawn to a method of treating weight loss by administering an agent which reduces sympathetic nervous system activity, or an agent which inhibits aldoserone effect or other aldosterone antagonists, to be used in the claimed method. antagonists. However, the written description in this case is only commensurate with claim 4, because instant specification does not disclose the structure of other agents that reduce sympathetic nervous system activity, or an other agents which inhibit aldoserone effect, or other aldosterone?

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). One of ordinary skill in the art would not be able to visualize the structure of the agents recited in claims 1, 2, 3, 19, 35, 36, 38, 39 and 41 to be used in the claimed method. As a result, it does not appear that the inventors were in possession of agents which reduce sympathetic nervous system activity or other agents which inhibit aldosterone effect or other aldosterone antagonists, other than those recited in claim 4, to be used in the claimed method.

Claim rejections-35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 1-4, 19, 29-31 and 41 are rejected under 35 U.S.C § 102(b) as being anticipated by RALES investigators (October 1996).

(Instant claims 1-4, 19, 29-31 and 41) are interpreted as being drawn to a method of treating an underlying disease that causes weight loss by administering an agent).

The RALES researchers disclose a method of treating patients with chronic heart failure with spironolactone (12.5-75mg/ml), in addition to diuretics and ACE inhibitors, (see abstract). The RALES' study demonstrates that daily doses of 12.5 to 25 mg of spironolactone co-administered with conventional therapy of ACE inhibitors, loop

diuretics, and digitalis are relatively safe and effective in blocking the effects of aldosterone, while reducing the potential for hypokalemia in patients with chronic congestive heart failure, (see abstract and page 906, column 2). Therefore, the RALES reference meets the limitations recited in instant claims1-4, 19, 29-31 and 41. With respect to the effect on weight loss recited in the claims, it would be an inherent property of spironolactone to reduce weight loss in patients. The RALES study discloses patients suffering from chronic heart failure (claims 31, 41, 29, 19), that are being treated with spirononlactone (claim 4). Therefore, the effect of spironolactone on body weight is a newly discovered result of a known process directed to the same purpose, which does not make the instant method patentable because such result is inherent. See MPEP 2112-2112.02.

With respect to claims 1 and 19, spironolactone administered by the RALES researchers reduces a sympathetic nervous system activity, because it inhibits aldosterone and it also affects cardiovascular reflexes because it decreases both systolic and diastolic arterial pressures (see page 905, top of column 2).

Therefore the RALES reference anticipates the instant claims 1-4, 19, 29-31 and 41 in the absence of any evidence to the contrary.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-

0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
24 April 2004

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